K091633
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TEPHA
MEDICAL DEVICES

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Section X
Summary of Safety and Effectiveness
(Prepared June 22, 2012)

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Tepha, Inc. is submitting the following summary of information respecting safety and effectiveness:

Trade Name:	TephaFLEX® Surgical Film
Sponsor:	Tepha, Inc. 99 Hayden Avenue, Suite 360 Lexington, MA 02421 Telephone: 781.357.1700 Fax: 781.357.1701
Contact Person:	Mary P. LeGraw, V.P., Regulatory Affairs
Device Classification Name:	CFR §878.3300 – OOD, PAJ Surgical Mesh
Classification:	According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.
Predicate Devices:	Tepha, Inc. – TephaFLEX Surgical Film Tepha, Inc. - TephaFLEX Absorbable Mesh MAST Biosurgery, Inc. – Surgi-Wrap Film
Device Description:	TephaFLEX surgical film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera. **Note:** The TephaFLEX surgical mesh is not intended to be placed transvaginally The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy
Safety and Performance:	Mechanical testing, *in vivo* animal testing, and biocompatibility testing, were performed based on recommendations identified in the FDA surgical mesh guidance document: The Guidance for the Preparation of a Pre-market Notification Application for a Surgical Mesh. Specifically, comparative burst strength, suture pull-out strength, tensile strength and tear resistance strength was characterized. *In vivo* strength retention was characterized via a subcutaneous implantation study.
Conclusion:	Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX surgical film has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Tepha, Incorporated
% Ms. Mary P. LeGrew
Vice President, Regulatory Affairs
99 Hayden Avenue, Suite 300
Lexington, Massachusetts 02421

AUG 24 2012

Re: K091633
Trade/Device Name: TephaFLEX® Surgical Film
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OOD, PAJ
Dated: June 3, 2009
Received: June 4, 2009

Dear Ms. LeGrew:

This letter corrects our substantially equivalent letter of August 7, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091633

Device Name: TephaFLEX® Surgical Film

Indications for Use:

TephaFLEX® Surgical Film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

NOTE: The TephaFLEX Surgical Film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

Prescription Use: X AND/OR Over-The-Counter ___
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091633